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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/674,148      | 09/29/2003  | Hayley Zen           | 27053/2062          | 1916             |

29933 7590 03/23/2006  
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EXAMINER

OWENS, AMELIA A

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1625

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                   |  |
|------------------------------|--------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/674,148 | <b>Applicant(s)</b><br>ZEN ET AL. |  |
|                              | <b>Examiner</b><br>Amelia A. Owens   | <b>Art Unit</b><br>1625           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 8-13 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

1. Claims 3-7 have been canceled. New claims 8-13 have been added. Claims 1,2,8-13 are pending. No drawings filed.

#### *Claim Rejections - 35 USC § 102*

2. The rejection of claims 3-7 under 35 USC 102(b) over Bi (2000) is dropped as the claims have been canceled.

3. The rejection of claims 1,2 under 35 USC 102(b) over Bi (2000) is dropped as the claims have been amended creating a clear demarcation over the art.

4. The rejection of claims 1,2 under 35 USC 102(b) over Bi (2002) is dropped as the claims have been amended creating a clear demarcation over the art.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bi (2000) already of record.

Bi generically the claimed process for producing compounds similar to those claimed. See results and discussion section at page 2669; page 9 of the specification. Note the scheme is the same.

Applicant's remarks are noted. However, one of ordinary skill in the art would thus be motivated to prepare compounds according to Bi as Bi clearly using the same reactants/reaction mechanism to prepare structurally similar compounds. A process which from the results obtained, is analogous to a prior art process is not patentable merely because the product thereof

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is novel and patentable. *Clinical Products Ltd v. Brenner*, Comr Pats, 149 USPQ 475. Further, the mere use of different starting materials, in a conventional process to produce the product one would expect therefrom does not render the process novel/unobvious. In re Kanter, 158 USPQ 331. Note applicants process in step d uses N-benzoylaminoglycol; P-methylbenzene (toluene) sulfonic acid is derived from the same family as P-nitrobenzene sulfonic acid.

Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Bi in the expectation of obtaining a useful protein kinase C inhibitor compound as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in In re Lohr 137 USPQ 548 at 549 (CCPA 1963), and in In re Payne 204 USPQ 249 at 254 (CCPA 1979).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For compounds of formula 22 and 30, the "P" is missing in front of the NO<sub>2</sub>C<sub>6</sub>H<sub>4</sub> and NH<sub>2</sub>C<sub>6</sub>H<sub>4</sub> groups respectively. Compare with claim 1 filed 9/29/2003.

Compounds of formulas 22/23 and 34/35 are the same formula. The formula only need appear once in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the factors have been considered but only the most relevant will be discussed below.

**The nature of the invention:** The nature of the invention is the method of inhibiting protein kinase C, comprising contacting said protein kinase C with the claimed compounds. See claims.

**The state of the prior art and predictability:** The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease).

A slight change in the structure of the compound would drastically change its biological activity in vitro. In the in vivo system, the degree of unpredictability multiplies in view of the complexity of the physiological conditions.

**Guidance and working examples:** Compounds according to the invention have been made. The data @ pages 22-25 is noted. It is not seen where the specification teaches how to contact PKC with the claimed compound. Further, contact per se is not a viable utility. What desired effect are applicants achieving?

Since insufficient guidance and teaching have been provided by the specification, the skilled artisan, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation.

#### ***Claim Objections***

8. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Certain Observations***

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9. Claim 13 is allowed. The prior art does not teach or suggest the claimed compounds or their use as protein kinase C (PKC) inhibitors. Bi (2000) teach structurally similar compounds which target PKC. Structurally similar compounds would be expected to have similar properties.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

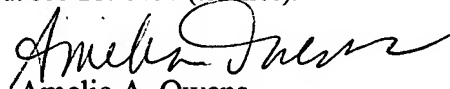
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Amelia A. Owens  
Primary Examiner  
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